#### REMARKS

Claims 1-27 are currently pending in this application. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and specification and the following remarks.

# I. Specification:

### A. Drawings

The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because they included the reference element "ALPHA" not mentioned in the description. In response, the description has been amended (i.e. paragraph 45 on page 4, lines 29-33) to define the reference element "ALPHA." Applicant respectfully requests that the objection be withdrawn.

### **B.** Specification

Applicant voluntarily undertook to correct various grammatical informalities discovered in the specification, including: (a) changing "portions 20A and 20" to "portions 20A and 20B" in paragraph 39 (page 4, line 33); and (b) changing "proved" to "provided" in paragraph 42 (page 5, line 13). No new matter has been introduced through any of these amendments.

#### II. Claims:

# A. Objections - Informalities

Claim 1 was objected for reciting "top position" and "bottom position" as opposed to "top portion" and "bottom portion." Claim 1 has been amended to incorporate these changes such that the objection should now be withdrawn as moot.

# B. Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph

Claims 21-22 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, claims 21 and 22 were rejected for failing to include sufficient antecedent basis for the limitation "the surgical cannulae." In response, Applicant has amended claim 20 (from which claims 21 and 22 depend) to include the limitation "surgical cannulae." As such, Applicant respectfully requests that the rejection of claims 21 and 22 be withdrawn as moot.

# C. Claim Rejections - 35 USC § 102 (e),

Claims 1-5, 9-11, 14, 17, 23-26 and 27 were rejected as being anticipated by U.S. Patent No. 6,224,631 to Kohrs ("Kohrs"). Applicant respectfully traverses these rejections as follows.

In order to reject a claim for anticipation, it must be shown that each and every element of the claim can be found in a single reference. In order to avoid rejection for anticipation, an applicant need only show that the claim contains at least one element not disclosed in the cited reference.

Claim 1, as amended, recites an intervertebral support system including a center portion, a top portion, and a bottom portion. The center portion is dimensioned to be positioned in an intervertebral space, and includes top and bottom recesses facing generally cranially and caudally when the center portion is positioned within the intervertebral space. The top portion

has a bottom recess facing generally caudally and interlocking with the top recess in the center portion when the top portion is positioned on top of the center portion within the intervertebral space. The bottom portion has a top recess facing generally cranially and interlocking with the bottom recess in the center portion when the center portion is positioned on top of the bottom portion within the intervertebral space.

The Kohrs reference does not appear to disclose each and every element of claim 1. More specifically, Kohrs fails to disclose (among other things) the claimed feature of providing a "a center portion...having top and bottom recesses facing generally cranially and caudally when the center portion is positioned within the intervertebral space," much less a "a top portion having a bottom recess facing generally caudally and interlocking with the top recess in the center portion when the top portion is positioned on top of the center portion within the intervertebral space" or a "a bottom portion having a top recess facing generally cranially and interlocking with the bottom recess in the center portion when the center portion is positioned on top of the bottom portion within the intervertebral space."

Kohrs discloses a spinal implant 10 including an upper transverse member 1, a lower transverse member 2, and a central support member 3, with channels 24a, 24b formed between the transverse members 1, 2 and the central support member 3. The spinal implant 10 of Kohrs is of unibody construction (see Claim 1, line 3), as opposed to the separable portions of the present invention. Moreover, the channels 24a, 24b of Kohrs (to the extent they are analogous to the recesses of the present invention - which Applicant does not concede) are not oriented caudally or cranially as with the recesses of the present invention.

Because Kohrs appears silent with regard to at least one element of amended Claim 1, it is respectfully requested that the rejection of Claim 1 be withdrawn. Claim 1 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 2-5, 9-11 and 14, being dependent upon and further limiting independent Claim 1, should be allowable for the reasons set forth in support of the allowability of Claim 1, as well as the additional recitations they contain.

Claim 17, as amended, recites a method of supporting adjacent vertebrae by assembling an intervertebral support assembly between adjacent vertebrae. The method includes the steps of: (a) providing a bottom portion having a top recess, a top portion having a bottom recess, and a center portion having a top recess and a bottom recess; (b) advancing the center portion into a patient's intervertebral space such that the top and bottom recesses face generally cranially and caudally within the intervertebral space; (c) advancing the top portion into the patient's intervertebral space such that the bottom recess faces generally caudally within the intervertebral space and interlocks with the top recess of the center portion; and (d) advancing the bottom portion into the patient's intervertebral space such that the top recess faces generally cranially within the intervertebral space and interlocks with the bottom recess in the center portion.

Kohrs appears to be silent regarding the claimed step of "providing a bottom portion having a top recess, a top portion having a bottom recess, and a center portion having a top recess and a bottom recess," as well as the steps (b)-(d) of advancing the center, top and bottom

portions into the intervertebral space such that the respective caudally and cranially facing recesses engage to interlock and couple the support system together. Instead, the spinal implant 10 of Kohrs is of unibody construction, such that it is incapable of being introduced in separate pieces, as found in steps (b)-(d) of Claim 17.

Because Kohrs appears silent with regard to at least one element of amended Claim 17, it is respectfully requested that the rejection of Claim 17 be withdrawn. Claim 17 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 23-25, being dependent upon and further limiting independent Claim 17, should be allowable for the reasons set forth in support of the allowability of Claim 17, as well as the additional recitations they contain.

Claim 26, as amended, recites an intervertebral support system including a bottom portion and a top portion. The bottom portion has a top recess facing generally cranially when the bottom portion is positioned within an intervertebral space. The top portion has a bottom recess facing generally caudally and interlocking with the top recess of bottom portion when the top portion is positioned on top of the bottom portion within the intervertebral space.

Kohrs fails to teach or describe the feature of providing "a bottom portion having a top recess facing generally cranially when the bottom portion is positioned within an intervertebral space," much less "a top portion having a bottom recess facing generally caudally and interlocking with the top recess of bottom portion when the top portion is positioned on top of the bottom portion within the intervertebral space." Rather, as described above, the spinal implant 10 of Kohrs is of unibody construction, as opposed to the separable portions of the present invention, and the channels 24a, 24b (to the extent they are analogous to the recesses of the present invention – which Applicant does not concede) are *not* oriented caudally or cranially as with the recesses of the present invention.

Because Kohrs appears silent with regard to at least one element of amended Claim 26, it is respectfully requested that the rejection of Claim 26 be withdrawn. Claim 26 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claim 27, as amended, recites a method of supporting adjacent vertebrae by assembling an intervertebral support assembly between adjacent vertebrae. The method includes the steps of: (a) providing a bottom portion having a top recess, and a top portion having a bottom recess; (b) advancing the bottom portion into a patient's intervertebral space such that the top recess faces generally cranially; and (c) advancing the top portion into the patient's intervertebral space such that the bottom recess faces generally caudally and interlocks with the top recess on the bottom portion.

Kohrs fails to teach or describe the claimed step of "providing a bottom portion having a top recess, and a top portion having a bottom recess," nor the steps of "advancing the bottom portion into a patient's intervertebral space such that the top recess faces generally cranially" or "advancing the top portion into the patient's intervertebral space such that the bottom recess faces generally caudally and interlocks with the top recess on the bottom portion." Instead, as

described above, the spinal implant 10 of Kohrs is of unibody construction, as opposed to the separable portions of the present invention, and the channels 24a, 24b (to the extent they are analogous to the recesses of the present invention – which Applicant does not concede) are not oriented caudally or cranially as with the recesses of the present invention.

Because Kohrs appears silent with regard to at least one element of amended Claim 27, it is respectfully requested that the rejection of Claim 27 be withdrawn. Claim 27 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

## D. Claim Rejections - 35 USC §103(a),

Claims 6-7, 12-13 and 15 were rejected as being unpatentable over Kohrs and/or in view of U.S. Patent No. 6,241,769 to Nicholson et al ("Nicholson") and/or U.S. Patent No. 5,192,327 to Brantigan ("Brantigan"). Applicant respectfully traverses these rejections as follows.

Claims 6-7, 12-13 and 15 depend from independent claim 1. As described above, Kohrs fails to disclose the Claim 1 feature of providing a "a center portion...having top and bottom recesses facing generally cranially and caudally when the center portion is positioned within the intervertebral space," much less a "a top portion having a bottom recess facing generally caudally and interlocking with the top recess in the center portion when the top portion is positioned on top of the center portion within the intervertebral space" or a "a bottom portion having a top recess facing generally cranially and-interlocking with the bottom recess in the center portion when the center portion is positioned on top of the bottom portion within the intervertebral space."

The Nicholson and Brantigan references do not appear to make up for this significant deficiency in the Kohrs reference. Given this void in the teachings of Kohrs, Nicholson, and Brantigan (whether considered alone or in combination), it is respectfully submitted that one of ordinary skill in the art would not have been led to the invention as set forth in dependent claims 6-7, 12-13 and 15. Based on the foregoing, it is respectfully requested that the rejection of claims 6-7, 12-13 and 15 be withdrawn in favor of an indication of allowance.

Claims 20-22 were rejected as being unpatentable over Kohrs in view of Brantigan.

Applicant respectfully traverses these rejections as follows. As described above, the Kohrs reference appears to be silent regarding the claim 17 step of "providing a bottom portion having a top recess, a top portion having a bottom recess, and a center portion having a top recess and a bottom recess," as well as the steps (b)-(d) of advancing the center, top and bottom portions into the intervertebral space such that the respective caudally and cranially facing recesses engage to interlock and couple the support system together. Instead, the spinal implant 10 of Kohrs is of unibody construction, such that it is incapable of being introduced in separate pieces, as found in steps (b)-(d) of Claim 17.

The Brantigan reference similarly appears to be silent regarding the features of independent Claim 17. With both references failing in this regard, there would be no reason why one skilled in the art would be led to the present invention as presently set forth in Claims 20-22. Based on the foregoing, it is respectfully requested that the rejection of claims 20-22 be withdrawn in favor of an indication of allowance.

## E. Allowable Subject matter

Claims 8, 18, and 19 were objected to as being dependent on a rejected base claim, but deemed allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In response, Claims 8, 18, and 19 have been rewritten in independent form per the Examiner's suggestion such that they are now believed to be in proper form for allowance.

## **CONCLUSION**

Reconsideration and allowance of the claims in this application is respectfully requested.

In the event that there are any questions concerning the remarks above or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted, NUVASIVE, INC.

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